

## REMARKS

Applicants note that all amendments, cancellations, and additions of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Office Action mailed February 19, 2009, the Examiner issued several rejections. Each of the rejections is discussed in detail below.

### **I. Interview Summary**

On May 20, 2009, Applicants representatives Tanya Arenson and David Casimir conducted a telephone interview with Examiner Cook. During the interview, the rejections under 35 U.S.C. 103 were discussed.

### **I. The Claims are Non-Obvious**

In the Office Action mailed February 19, 2009, the Examiner rejected Claims 1, 3-5, 8, 10 and 11 under 35 U.S.C. 103(a) as allegedly being obvious in light of Sangha (US 5,334,502; hereinafter Sangha) as evidence by Levitskii et al (Ukrainskii Biokimicheskii Zhurnal, 1979, 51:3, p. 289; English abstract only; hereinafter Levitski) in view of Titmas (US 5,334,502; hereinafter Titmas). The Examiner further rejects Claims 6 and 12-15 under 35 U.S.C. 103 as allegedly being obvious in light of Sangha as evidenced by Levitski in view of Titmas and Bogema (US 6,248,598; hereinafter Bogema).

Applicants respectfully disagree. Applicants have provided arguments as to why the Examiner has not demonstrated a *prima facie* case of obviousness.<sup>2</sup> In particular, the Applicants note that the Examiner has not provided a motivation to combine the references with an expectation of success because the Examiner has not provided an expectation of success that potassium iodide would function in the assay of the presently claimed invention.

Nonetheless, the Applicants now provide the Declaration of Evan Singer, one of the inventors of the present invention. Mr. Singer's declaration states that the development of the

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).

<sup>2</sup> See Applicants' prior responses to office actions.

low cost, non-toxic, stable, easy to use, quantitative, colorimetric alcohol testing methods embodied by the methods of presently claimed invention presented a number of significant challenges. For example, the development of a detection chemistry that simultaneously was: 1) non-toxic (so that it could be placed into the mouth); 2) sensitive enough to detect low levels of alcohol; 3) able to reproducibly provide a detectable visible color; 4) provide a quantitative or semi-quantitative result; 5) provide “on/off” detection at particular alcohol levels; 6) not be triggered by other saliva components; and 7) be sufficiently durable to survive manufacture, shipping, and handling by customers required significant experimentation. Prior to the invention, Mr. Singer and the other inventors were not sure whether any such chemistry existed. In addition, Mr. Singer’s declaration states that the menu of possible chemistries was non-trivial and that there were a variety of different enzyme systems, including alcohol oxidase and dehydrogenase and numerous chromagens that could be mixed and matched with different enzyme systems. Mr. Singer’s declaration explains that, in order to arrive at the methods of the presently claimed invention, substantial investigation and experimentation was required. After much investigation and experimentation, potassium iodide, in combination with the claimed enzyme systems, was found to provide a non-toxic, stable, detectable, quantitative, on/off colorimetric chromagen that met all of the criteria needed. No other tested chromagens were found to work sufficiently. Mr. Singer’s declaration further states that if the inventors had not discovered this successful combination, it is unclear whether any other option would have been possible and that the various chromagens used in the prior art did not or would not work for one reason or another: too toxic, not sensitive enough, too high a level of false positives or false negatives. It cannot be said that any chromagens that function with alcohol dehydrogenase (the enzyme system used) are interchangeable with one another. Mr. Singer’s declaration notes that the experiments performed, and those of others demonstrated that the opposite is true: The potassium iodide was the needle in the haystack; most (and perhaps all) other chromagens are unsuitable in meeting all of the criteria for the user friendly test designed.

Accordingly, the Applicants submit that any *prima facie* case of obviousness<sup>3</sup> is rebutted by unexpected results described in Mr. Singer’s declaration. Accordingly, the Applicants submit that the claims are not obvious and respectfully request that the rejection be withdrawn.

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<sup>3</sup> The Applicants submit that the Examiner has not demonstrated a *prima facie* case of obviousness.

## CONCLUSION

All grounds of rejection of the Office Action mailed February 19, 2009, have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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